

What is Claimed is:

- 1 1. An orally administered pharmaceutical composition
2 comprising cyclosporine, ethanol, polyoxyethylene glycerol trioleate, and an oil
3 component.
- 1 2. The pharmaceutical composition of claim 1, wherein said
2 cyclosporine is cyclosporine A.
- 1 3. The pharmaceutical composition of claim 1, wherein said
2 cyclosporine is present at a concentration from about 5 to about 20% by weight.
- 1 4. The pharmaceutical composition of claim 3, wherein said
2 cyclosporine is present at a concentration from about 8 to about 12% by weight.
- 1 5. The pharmaceutical composition of claim 3, wherein said
2 cyclosporine is present at a concentration of 10% by weight.
- 1 6. The pharmaceutical composition of claim 1, wherein said oil
2 component is ethyl oleate.
- 1 7. The pharmaceutical composition of claim 1, wherein said
2 ethanol is present at about 15 to about 40 v/v%.
- 1 8. The pharmaceutical composition of claim 7, wherein said
2 ethanol is present at about 15 to about 25 v/v%.
- 1 9. The pharmaceutical composition of claim 7, wherein said
2 ethanol is present at 20 v/v%.
- 1 10. The pharmaceutical composition of claim 1, wherein said
2 polyoxyethylene glycerol trioleate is present at about 20 to about 50 v/v%.

1 11. The pharmaceutical composition of claim 1, wherein said oil
2 component is present at about 40 to about 65 v/v%.

1 12. The pharmaceutical composition of claim 11, wherein said oil
2 component is present at about 55 to about 65 v/v%.

1 13. The pharmaceutical composition of claim 11, wherein said oil
2 component is present at 60 v/v%.

1 14. An orally administered pharmaceutical composition
2 comprising cyclosporine, ethanol, polyoxyethylene glycerol trioleate and ethyl
3 oleate in a weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol
4 trioleate and ethyl oleate of about 5:18:25.9:50.1 to about 15:16:23.1:44.9.

1 15. The pharmaceutical composition of claim 14, wherein the
2 weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol trioleate and
3 ethyl oleate is 10:17.1:24.5:47.5.

1 16. The pharmaceutical composition of claim 15, wherein said
2 composition upon dilution with an aqueous media at a ratio of 1 part composition to
3 100 parts aqueous media forms a spontaneous emulsion.

1 17. The pharmaceutical composition of claim 16, wherein said
2 spontaneous emulsion comprises particles having a diameter of 50 to 185 nm.

1 18. A method of preparing an orally administered pharmaceutical
2 composition comprising the steps of:

3 dissolving cyclosporine in ethanol to form a solution;

4 combining polyoxyethylene glycerol trioleate and an oil
5 component with the solution to form a mixture; and

- 10 -

6 diluting the mixture with an aqueous media to allow formation
7 of a spontaneous emulsion.

1 19. The method of claim 18, further comprising the step of gently
2 mixing the diluted mixture to disperse the emulsion.

1 20. The method of claim 18, wherein the step of diluting further
2 comprises diluting 1 part of the mixture with 100 parts of aqueous media.

1 21. The method of claim 18, wherein said oil component is ethyl
2 oleate.

1 22. The method of claim 18, wherein said cyclosporine is
2 cyclosporine A.

1 23. The method of claim 18, wherein the cyclosporine is present at
2 a concentration of 10% by weight

1 24. The method of claim 18, wherein said ethanol is present at
2 about 15 to about 40 v/v%.

1 25. The method of claim 18, wherein said polyoxyethylene
2 glycerol trioleate is present at about 20 to about 50 v/v%.

1 26. The method of claim 18, wherein said oil component is present
2 at about 40 to about 65 v/v%.

1 27. The method of claim 18, wherein said composition comprises
2 cyclosporine, ethanol, polyoxyethylene glycerol trioleate and ethyl oleate in a
3 weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol trioleate and
4 ethyl oleate of 10:17.1:24.5:47.5.

- 11 -

1 28. The method of claim 27, wherein said spontaneous emulsion
2 comprises particles having a diameter of 50 to 185 nm.

1 29. The method of claim 28, wherein said spontaneous emulsion
2 comprises particles having a diameter of 50 to 150 nm.

1 30. The method of claim 17, wherein said spontaneous emulsion
2 comprises particles having a diameter of 50 to 150 nm.